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THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applications et al.

Serial No. 09/973,853

Filed: October 10, 2001

For: Aza- and Polyaza-Napthalenyl Carboxamides

Useful as HIV Integrase Inhibitors

Assistant Commissioner for Patents Washington, D.C. 20231

JAN 10 2002 PBARA BEI

Art Unit: 1614

Examiner: To Be Assigned

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention unless specifically designated as such. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

MERCK & CO., INC.

Date 1-10-2002

INFORMATION DISCLOSURE STATEMENT

4. Copies of the references listed on the attached form are not enclosed because they have been submitted to or cited by the Office in a related application as follows:

	RELATED APP	LICATION	
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE	
	ر		
upon which the instant application relies for an earlier filing date under 35 U.S.C. 120. Therefore, pursuant to 37 C.F.R. 1.98(d), copies of these references are not enclosed herewith. If this is inconvenient, additional copies will be submitted upon request.			
5. In accordance with 37 C.F.R. 1.97, (check one)			
the attached information is filed within three months of the filing da	te of the captioned case.		
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the attached information is filed more than three months after the filing date but prior to a first Official Action on the merits.

the attached information is being filed more than three months after the filing date and after receipt of the first Office Action on the merits, but before Final Action or Notice of Allowance. The enclosed authorization is therefore given to charge Deposit Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).

the undersigned certifies that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Statement.

the undersigned certifies that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application or, to the knowledge of the person signing the certification after making reasonable inquiry, was known to any individual designated under 37 C.F.R. 1.56(c) more than three months prior to the filing of the statement.

Respectfully submitted,

By: Kenneth R. Walton

Attorney For Applicant(s)

Reg. No. 32,951

MERCK & CO., INC.

Patent Dept., RY60-30

P.O. Box 2000

Rahway, N.J. 07065-0907

(732)594-3462

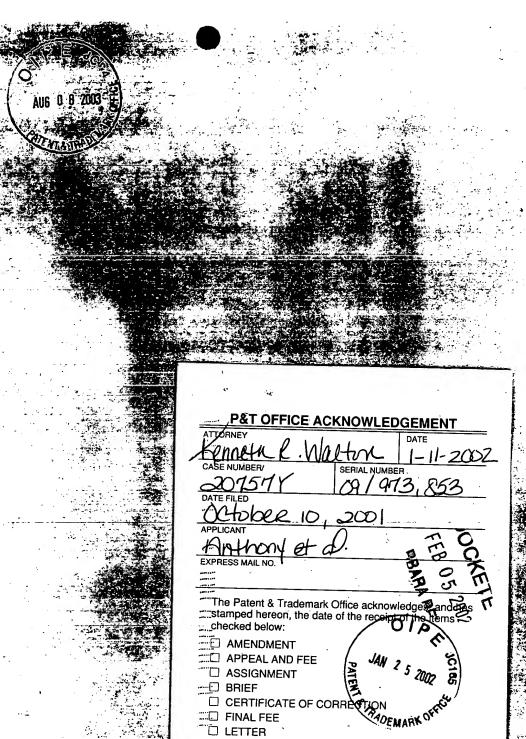
Date: January 10, 2002



P&T OFFICE ACKNOWLEDGEMENT
ATTORNEY DATE
Kanney K. Watter 1-10-2002
CASE NUMBER/ SERIAL NUMBER
20157Y 09/973,853
DATE FILED
October 10, 2001 -
APPLICANT
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☐ APPEAL AND FEE ☐ ASSIGNMENT
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BRIEF
☐ CERTIFICATE OF CORRECTION
☐ FINAL FEE
□ LETTER
☐ REQUEST FOR F.F. LICENSE
INFORMATION DISCLOSURE STATEMENT
PTO 1449 & REFERENCES
□ PETITION FOR EXTENSION OF TIME & FEE
☐ INVITATION TO CORRECT
□ DEMAND-CHAPTER II & FEE SHEET
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P&T OFFICE ACKNOWLEDGEMENT
ATTORNEY DATE
Kenneta R. Walter 1-11-2002
CASE NUMBER/ SERIAL NUMBER
20157Y 109/913,853
DATE FILED
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APPLICANT
EXPRESS MAIL NO
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ASSIGNMENT
☐ BRIEF
☐ CERTIFICATE OF CORRECTION ☐ FINAL FEE
☐ LETTER
☐ BEQUEST FOR F.F. LICENSE
INFORMATION DISCLOSURE STATEMENT
☐ PTO 1449 & REFERENCES
PETITION FOR EXTENSION OF TIME & FEE
☐ INVITATION TO CORRECT
DEMAND-CHAPTER II & FEE SHEET



BEQUEST FOR F.F. LICENSE

INFORMATION DISCLOSURE STATEMENT

PTO 1449 & REFERENCES
PETITION FOR EXTENSION OF TIME & FEE

..... INVITATION TO CORRECT

☐ DEMAND-CHAPTER II & FEE SHEET

F4424

AUG 0 8 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applications and Anthony et al.

Serial No. 09/973,853

Filed: October 10, 2001

For: Aza- and Polyaza-Napthalenyl Carboxamides

. Useful as HIV Integrase Inhibitors

Assistant Commissioner for Patents Washington, D.C. 20231

Art Unit: 1614

Examiner: To Be Assigned

OCKETE 2002

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MERCK & CO., INC.

Date <u>2-4-200</u>2

INFORMATION DISCLOSURE STATEMENT

4. Copies of the references listed on the attached form are not enclosed because they have been submitted to or cited by the Office in a related application as follows:

·		RELATED APPLICATION		
	U. S. SERIAL NUMBER	FILING DATE	MERCK CASE	
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37	C.F.R. 1.98(d), copies of these references are not enclosed herew	ith. If this is inconvenient, a	additional	
cot	pies will be submitted upon request.			
	5. In accordance with 37 C.F.R. 1.97, (check one)			
	the attached information is filed within three months of the filing d	ate of the captioned case.		
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	the attached information is being filed more than three months aft Action on the merits, but before Final Action or Notice of Allowand to charge Deposit Account No. 13-2755 for the fee required under	ce. The enclosed authorizat		
	the undersigned certifies that each item of information contained in a communication from a foreign patent office in a counterpart to the filing of this Statement.	in this Information Disclosur oreign application not more	e Statement was cited than three months prio	
	the undersigned certifies that no item of information contained in a communication from a foreign patent office in a counterpart fore signing the certification after making reasonable inquiry, was known 1.56(c) more than three months prior to the filing of the statement	eign application or, to the kn wn to any individual designa	owledge of the person	
		Respectfully submitted,		
		By: Kenneth R. Walton	alton	
		Attorney For App	licant(s)	
		Reg. No. <u>32,951</u>	· 	
		MERCK & CO., INC.	•	

Patent Dept., RY60-30

Rahway, N.J. 07065-0907

Date: February 4, 2002

P.O. Box 2000

(732)594- 3462



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P&T OFFICE ACKNOWLEDGEMENT	
ATTORNEY ATTORNEY ATTORNEY CASE NUMBERV CASE NUMBERV SERIAL NUMBER OP 1913, 853 DATE FILED OCKETE APPLICANT APP	•
The Patent & Trademark Office acknowledges, and has stamped hereon, the date of the receipt of the items checked below: AMENDMENT APPEAL AND FEE ASSIGNMENT BRIEF CERTIFICATE OF CORRECTION FINAL FEE LETTER	
REQUEST FOR F.F. LICENSE INFORMATION DISCLOSURE STATEMENT PTO 1449 & REFERENCES PETITION FOR EXTENSION OF TIME & FEE INVITATION TO CORRECT DEMAND-CHAPTER II & FEE SHEET	

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Anthony et al.

Serial No.: 09/973,853

Art Unit:

1614

Docket No.:

20757Y

Examiner:

Filed:

October 10, 2001

Not Yet Assigned

For:

AZA- AND POLYAZA-NAPHTHALENYL CARBOXAMIDES

USEFUL AS INTEGRASE INHIBITORS

Assistant Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In compliance with 37 C.F.R. 1.97, submitted herewith on the attached form is a citation to a patent document, a copy of which is enclosed. The submission and listing of this reference is not to be construed as an admission that the reference is "prior art" with respect to the claimed invention. In accordance with 37 CFR §1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made. In addition, in accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

It is requested that the Examiner consider the cited reference as part of the examination of the subject application, make the reference of record, and return an initialed copy of the attached form with the next communication to Applicants.

This statement is being filed more than three months after the filing date but prior to a first Official Action on the merits. Accordingly, no fee is due. In the event a first Official Action on the merits has already been mailed, but has not yet been received, it is still believed that no fee is due, because the undersigned certifies that each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

MERCK & CO., INC.

Вv

Kenneth R. Walton, Reg. No. 32,951

Attorney for Applicants

Respectfully submitted,

MERCK & CO., Inc. P.O. Box 2000

Rahway, New Jersey 07065-0907

Tel.: (732) 594-3462

Date: July 10, 2002



P&T OFFICE ACKNOWLEDGEMENT

7-10-2002 Kenneth R. Walton SERIAL NUMBER 09/973,853 CASE NUMBER/ 20757Y DATE FILED October 10, 2001 Neville J. Anthony, et al. APPLICANT EXPRESS MAIL NO.

The Patent & Trademark Office acknowledges, and has stamped hereon, the date of the receipt of the items checked below:

... AMENDMENT

☐ APPEAL AND FEE

☐ · ASSIGNMENT

☐ BRIEF

☐ BRIEF
☐ CERTIFICATE OF CORRECTION

FINAL FEE

LETTER

☐ REQUEST FOR F.F. LICENSE

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X PTO 1449 & REFERENCES (att. 1 ref.)

☐ PETITION FOR EXTENSION OF TIME & FEE

☐ INVITATION TO CORRECT

☐ DEMAND-CHAPTER II & FEE SHEET

F4424

IN THE CONTER 1600/2900

Applicants: Anthony, et al.

Serial No. 09/973,853

Filed: October 10, 2001

For: AZA- AND POLYAZA-NAPHTHALENYL

CARBOXAMIDES USEFUL AS INTEGRASE

INHIBITORS

Assistant Commissioner for Patents Washington, D.C. 20231

Art Unit: 1614

Examiner: Not Yet Assigned

DOCKETED

FEB 1 0 2003

LORI SCHEPISI

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97

Sir:

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- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- 3. Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.

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_	MERCK 8	& CO., INC.	
,BY		Date	



4. Ex	cept for Cite Nos, copies of the	references listed	on the attached for	m are not enclosed
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cited in	dersigned certifies that each item of information c any communication from a foreign patent office prior to the filing of this Statement.			
a comr person	dersigned certifies that no item of information con nunication from a foreign patent office in a counte signing the certification after making reasonable 1.56(c) more than three months prior to the filing	erpart foreign ap _l inquiry, was kno	plication, and, to the wn to any individual	knowledge of the
• .		Resp	ectfully submitted,	
		X eu	wille R. Wall Kenneth R. Walton	ton
		Attorr		licant(s)
		Reg.	No. <u>32,951</u>	-
			CK & CO., INC. at Dept., RY60-30	
	•	P.O. I	Box 2000	7
•			ay, N.J. 07065-090 594- <u>3462</u>	<i>(</i>
		•	February 10, 2003	



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Kenneth R. Walton		2-10-2003
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PATENT Case No

ES PATENT AND TRADEMARK OFFICE

Applicants: Anthony et al.

Serial No. 09/973,853

Filed: October 10, 2001

For: AZA- AND POLYAZA-NAPHTHALENYL

CARBOXAMIDES USEFUL AS INTEGRASE

Assistant Commissioner for Patents Washington, D.C. 20231

Art Unit: 1614

Examiner: Not Yet Assigned

FEB 25 2003

INFORMATION DISCLOSURE STATEMENTON SCHEPISI **UNDER 37 CFR 1.97**

Sir:

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February 24, 2003
EL 920762575 US
I HEREST CERTIFY THAT THE CORRESPONDENCE IS
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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Washington, D.C. 20231, on the date appearing below.

MERCK 8	s CO., ИС.
Ву	Date

Computer generated form "IDS Letter" (IDS Folder), Merck & Co., Inc. 06/20/2002



INFORMATION DISCLOSURE STATEMENT

caus	e they have been submitted to or cited by the Office in a re	elated application as follows:			
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•		Respectfully submitted,			
		Kuutte R. L. By: Kenneth R. Waltor	Jalton		
		Attorney For A Reg. No. 32,951			
		MERCK & CO., INC. Patent Dept., RY60-30 P.O. Box 2000 Rahway, N.J. 07065-0	907		
	and the second s	(732)594- <u>3462</u>			



P&T OFFICE ACKNOWLEDGEMENT				
ATTORNEY	:	DATE		
Kenneth R. Walto	n	2-24-2003		
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Anthony et al.	FEB 2 4	2003		
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Page 1 8 I PARTIE 8

PATENT Case No. 20757 AUG 1

N THE UNITED STATES PATENT AND TRADEMARK OFFIC

Application Meville J. Anthony, et al.

Serial No. 09/973,853

Filed: October 10, 2001

For: AZA- AND POLYAZA-NAPHTHALENYL

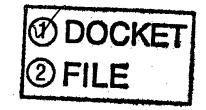
CARBOXAMIDES USEFUL AS INTEGRASE

INHIBITORS

Assistant Commissioner for Patents Washington, D.C. 20231

Art Unit: 1614

Examiner: Not Yet Assigned



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APR 2 % 1883

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MERCK & CO., INC.

By Markelloneus Date 4/2-3/03

INFORMATION DISCLOSURE STATEMENT

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	Respectfully submitted,			
	Kerneth R. Was	ton		
	By: Kenneth R. Walton			
	Attorney For App	licant(s)		
	Reg. No. <u>32,951</u> MERCK & CO., INC.	 .		
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	Patent Dept., RY60-30 P.O. Box 2000 Rahway, N.J. 07065-090	,		

Date: April 23, 2003



RECENTER 12 2003

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Anthony et al.

Serial No .:

09/973,853

Case No.: 20757Y

Art Unit:

1614

Filed:

October 10, 2001

For:

AZA- AND POLYAZA-NAPHTHALENYL

CARBOXAMIDES USEFUL AS INTEGRASE

INHIBITORS

Examiner:

Not Yet Assigned

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 DOCKETED JUL 15 2003 LORI SCHEPISI

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants submit the following information which they believe may be pertinent to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 C.F.R. § 1.56:

PART A

Before the filing date of the instant application, the Istituto di Ricerche di Biologia Molecolare P. Angeletti S.P.A. (IRBM) located in Italy disclosed in confidence to certain Merck employees including one or more of the applicants of the instant application certain 5,6dihydroxypyrimidine-4-carboxamides and suggested that these compounds might be

CERTIFICATE OF MAILING

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450, ON THE DATE APPEARING BELOW.

MERCK & CO., INC.

active as HIV integrase inhibitors. Representative of the earliest compounds disclosed by IRBM are 2-thienyl-substituted compounds of Formula A:

wherein R is

$$X^2$$
, wherein X^2 is H or Cl;

$$X^3$$
, wherein X^3 is CF_3 , OCH_3 , or X^3

, wherein
$$Y^1$$
 and Y^2 are both OCH3 or both Cl;

$$Y^4$$
 Y^3 , wherein (Y^3, Y^4) is either (Cl, F) or (Cl, CH₃);

$$G^{d^{2}}$$
 $G^{d^{2}}$
 G^{d

IRBM conducted further research on the dihydroxypyrimidine carboxamide series of compounds which led to the filing of patent applications WO 03/35076 and WO 03/35077, each of which is cited in a Form 1449 accompanying this statement (see Part B below). IRBM periodically communicated in confidence to certain Merck employees including one or more of

the applicants of the instant application on the progress of their work leading up to these patent filings, and accordingly many, though not all, of the compounds described in WO 03/35076 and WO 03/35077 were known to the applicants before the filing date of the instant application.

Before the filing date of the instant application all of the compounds of Formula A specified above and many, though not all, of the compounds described in WO 03/35076 and WO 03/35077 were tested for HIV integrase inhibition activity at Merck in the United States after their preparation in Italy.

IRBM also disclosed in confidence before the filing date of the instant application certain dihydroxypyrimidine carboxylic acids as viral polymerase inhibitors, especially as inhibitors of the hepatitis C virus polymerase enzyme. These compounds are described in WO 02/06246, which is cited in the accompanying Form 1449 (see Part B below). Many of these compounds were also tested for HIV integrase inhibiting activity at Merck in the United States before the filing date of the instant application.

IRBM also prepared the following two naphthyridine compounds before the filing date of the instant application:

$$CF_3CO_2$$
 $HN+$
 H_2N
 O OH and O OH

The preparation of these compounds was communicated in confidence to certain Merck employees including one or more of the applicants of the instant application before its filing date. These compounds were tested in Italy against HCV polymerase and tested against HIV integrase at Merck in the United States before the filing date of the instant application.

The subject matter developed and disclosed by IRBM and the invention claimed in the instant application were not owned by the same person or subject to an obligation of assignment to the same person at the time the invention was made.

PART B

In compliance with 37 C.F.R. 1.97, submitted herewith on the attached Form 1449 are citations to the following patent documents: US 6262055, US 6306891, US 6380249, WO

02/06246, WO 01/00578, WO 03/35076, and WO 03/35077. Copies of these documents are enclosed herewith.

PART C

U.S. Application Serial No. 10/260,029, filed June 6, 2003, is also brought to the Examiner's attention. This pending application corresponds to WO 01/00578 listed above. A copy of USSN 10/260,029 is enclosed herewith.

PART D

The subject matter disclosed and claimed in US 6306891, US 6380249, and USSN 10/260,029 was communicated in confidence to the applicants of the instant application before the filing date of the instant application. Subject matter contained in the above-cited US patents and applications and the invention claimed in the instant application were not owned by the same person or subject to an obligation of assignment to the same person at the time the invention was made.

The submissions in Parts A, B, C and D are not to be construed as admissions that any of the submitted information is "prior art" with respect to the claimed invention. In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made. In addition, in accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information disclosed is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).

It is requested that the Examiner consider the information set forth in Parts A, B, C and D and make it of record. It is further requested that the Examiner return an initialed copy of the attached form 1449 with the next communication to Applicants to signify that the statement has been considered and made of record.

This statement is being submitted more than three months after the filing of the instant application but before the mailing of the first Office Action on the merits. Accordingly, no fee is believed to be due.

Respectfully submitted,

Ву:

Kenneth R. Walton, Reg. No. 32,951

Attorney for Applicants

MERCK & CO., Inc.

P.O. Box 2000

Rahway, New Jersey 07065-0907

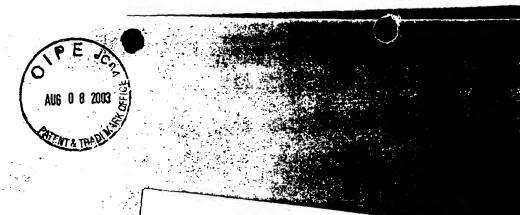
Tel.: (732) 594-3462

Date: July 14, 2003



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ATTORNEY	7/14/2003
Kenneth R. Walton	SERIAL NUMBER
CASE NUMBER/	09/973,853
20757Y	09/3/3,636
DATE FILED	
October 10, 2001	5
APPLICANT //	
Anthony et al.	
EXPRESS MAIL NO.	
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j	The Patent & Trademark Office acknowleds stamped hereon, the date of the receipt of the checked below: AMENDMENT APPEAL AND FEE ASSIGNMENT BRIEF CERTIFICATE OF CORRECT FINAL FEE LETTER REQUEST FOR F.F. LICENSE INFORMATION DISCLOSURE STATEMENT PTO 1449 & REFERENCES PETITION FOR EXTENSION OF TIME & F. INVITATION TO CORRECT DEMAND-CHAPTER II & FEE SHEET	A MAN ACTION

HIBIT 2

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Anthony et al.

Serial No .: 09/973,853 Case No.: 20757Y

Filed:

October 10, 2001

For:

Aza- and Polyaza-Napthalenyl Carboxamides Useful as

HIV Integrase Inhibitors

PATENT

Art Unit:

1614

Examiner:

To Be Assigned

Assistant Commissioner for Patents Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants also wish to bring the following co-pending PCT applications designating the U.S. to the Examiner's attention.

Appl'n No. PCT/US01/31:550, filed 10/09/01 Anthony et al:

Copies of these applications are enclosed herewith. Applicants hereby request that Examiner consider the above-listed co-pending cases, initial beside each to indicate that the co-pending applications have, in fact, been considered, and return a copy of the initialed page to Applicants.

Respectfully submitted,

By:

Kenneth R. Walton, Reg. No. 32,951

Attorney for Applicants

MERCK & CO., Inc.

P.O. Box 2000

Rahway, New Jersey 07065-0907

Tel.: (732) 594-3462

Date: January 11, 2002

AUG 0 8 2003

THE UNITED STATES PATENT AND TRADEMARK OFFICE CENTER 1

Applicants

Anthony et al.

Serial No .:

09/973,853

Case No.: 20757Y

Art Unit:

DOCKETED

1614

FEB 12 2003

Filed:

October 10, 2001

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AZA- AND POLYAZA-NAPHTHALENYL

CARBOXAMIDES USEFUL AS INTEGRASE

INHIBITORS

Not Yet Assigned

Assistant Commissioner for Patents

Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants wish to bring the following co-pending applications to the Examiner's

attention.

Case 20949Y

PCT Serial No. PCT/US 02/25666; Int'l Filing Date -- 13 Aug 2002

Merck & Co., Inc.

Case 20950Y

PCT Serial No. PCT/US 02/27151; Int'l Filing Date -- 13 Aug 2002

Merck & Co., Inc.

AC Case 20951Y

Serial No. 10/218,537, filed 14 Aug 2002

Anthony et al.

Applicants hereby request that Examiner consider the above-listed co-pending cases, initial beside each to indicate that the co-pending applications have, in fact, been considered, and return a copy of the initialed page to Applicants. Enclosed are copies of these applications as originally filed.

MAILED BY 1

Respectfully submitted,

By:

Kenneth R. Walton, Reg. No. 32,951

Attorney for Applicants

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Date: February 12, 2003